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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,456	05/02/2001	Marie-Francoise Rosier-Montus	3806.0505	1457

5487 7590 05/17/2005

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EXAMINER
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LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/846,456

Applicant(s)

ROSIER-MONTUS ET AL.

Examiner

Gerald G. Leffers Jr., PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

Receipt is acknowledged of an amendment, filed on 2/15/2004, in which several claims were amended (1-3, 5, 15, 23). Claims 1-3 & 5-38 are pending in the instant application.

Any rejection of record not addressed herein is withdrawn. This action is Final.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These are new grounds of rejection that were necessitated by applicants' amendment of the claims in the response filed 2/15/2005.**

Claim 16 recites an isolated nucleic acid having at least 80% nucleotide identity to 500 or more consecutive nucleotides of the nucleotide sequence of SEQ ID NO: 1 or the complement of SEQ ID NO: 1.

Claim 24 recite an isolated nucleic acid that hybridizes under high stringency conditions 500 or more consecutive nucleotides of the nucleotide sequence of SEQ ID NO: 1 or the complement of SEQ ID NO: 1 where the isolated nucleic acid has transcriptional regulatory

Art Unit: 1636

activity. Claim 31 recites that the isolated nucleic acid of claim 24 activates the transcription of an operatively linked sequence. Claim 32 recites that the isolated nucleic acid of claim 24 inhibits the transcription of an operatively linked nucleic acid sequence.

The rejected claims encompass nucleic acids that must be 80% identical to or hybridize with a sequence of at least 500 consecutive nucleotides of SEQ ID NO: 1. For the embodiments directed to 80% sequence identity, this encompasses a minimum of 100 nucleotides that can be changed from the at least 500 consecutive nucleotides of SEQ ID NO: 1 where the modified nucleic acid must retain functional activity. SEQ ID NO: 1 is itself over 3.2 kb in length. While the specification provides a single, limiting definition for what constitutes stringent hybridization conditions, the number of nucleic acid molecules that might meet the structural limitations of the claims is large whereas the percentage of those that actually retain the ability to modulate transcription is likely to be far less. Nor has the prior art or specification provided a basis for the skilled artisan to envision those modifications to any consecutive 500 nucleotides of SEQ ID NO: 1 that are necessarily going to retain functional activity. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the broadly claimed genus of isolated nucleic acids that retain the recited function of modulating transcription of an operatively linked nucleic acid sequence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-3, 5-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 1636

regards as the invention. **These are new grounds of rejection that were necessitated by applicants' amendment of the claims in the response filed 2/15/2005.**

Claims 1-3 have been amended to read "the complement of SEQ ID NO:" in such a way that the claims can be interpreted to simply specify that the isolated nucleic acid comprises the complementary sequence to the one described by SEQ ID NOS: 1, 2 OR 3. For example, claim 1 could be read as reciting "[a]n isolated nucleic acid comprising a polynucleotide having...the complement of SEQ ID NO: 1." It would be remedial to amend the claim language to explicitly recite that the limitations with regard to the size of the polynucleotide apply to the entire complement sequence as well.

Similarly, claims 15 and 23 have been amended to read "the complement of SEQ ID NO: 1". Again, it would be remedial to amend the claims to explicitly recite that the 500 or more consecutive nucleotides limitation applies to "the complement of SEQ ID NO: 1 as well".

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1636

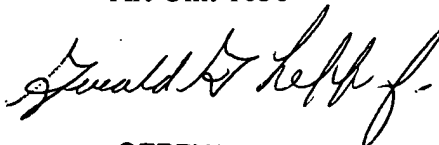
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636



**GERRY LEFFERS  
PRIMARY EXAMINER**

ggj